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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)/APPLICANT(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
ZIV	KARNI	CAESAREA, ISRAEL
ALEXANDER	BRITVA	MIGDAL HA'EMEK, ISRAEL

☐ Additional inventors are being named on page 2 attached hereto

TITLE OF THE INVENTION (280 characters max)

IMPROVED SYSTEM AND METHOD FOR HEATING BIOLOGICAL TISSUE VIA RF ENERGY

CORRESPONDENCE ADDRESS

Direct all correspondence to:

☐ Customer Number [ ] → Place Customer Number Bar Code Label here

OR

☐ Firm or Individual Name	Mark M. Friedman				
Address	c/o POLKINGHORN				
Address	9003 FLORIN WAY				
City	UPPER MARLBORO	State	MD	ZIP	20772
Country	US	Telephone	301-952-1011	Fax	301-952-9023

ENCLOSED APPLICATION PARTS (*check all that apply*)

☒ Specification — Number of Pages: 14 — Applicant is Small Entity

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Respectfully submitted,

SIGNATURE

DATE 11 JAN 05

TYPED or PRINTED NAME Mark M. Friedman

REGISTRATION NO. (*if appropriate*) 33,883

TELEPHONE (703) 415-1581

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P19LARGE/REV04

APPLICATION FOR PATENT

Inventor(s): ZIV KARNI AND ALEXANDER BRITVA

Title: IMPROVED SYSTEM AND METHOD FOR HEATING BIOLOGICAL TISSUE VIA RF ENERGY

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to an improved system and method for heating biological tissue via RF energy and, more particularly, to a system and method which rely upon a single electrode. Control of phase, pulse width modulation and/or duty cycle of applied RF waves obviate the need for cooling of the skin surface while facilitating efficient heating of underlying layers of tissue such as dermis and subcutaneous layers. Specifically, heating and contraction of adipose tissues as a means of cellulite reduction is achieved.

Adipose tissues, particularly cellulite, are typically treatable only with a strict regimen of diet and exercise. Patient compliance with these previously available regimens is poor. Cellulite occurs when fat cells swell compressing the flow of blood and lymph. This leads to build-up of fluid and toxins. Connective tissue forms hard fibrous capsules around the fat cells. This results in a "lumpy" appearance. The fat cells involved are located primarily in the third and most deep (skin) layer, which has a variable by thickness depending on the amount fat in the subject. Thickness of this layer typically increases in areas such as abdomen, thighs and buttocks.

Previously proposed methods for cellulite treatment include Topical treatment, Teas and capsules, Cellulite wraps, Endermologie, Mesotherapy, Acthyderm and

Ultrasonic and particularly focused ultrasonic treatment. These techniques have not demonstrated clinical efficacy in reducing the "lumpy" appearance associated with cellulite deposits.

In addition, thermotherapy using electromagnetic radiation or radio-frequency (RF) waves has been proposed. RF treatment is more effective than other available therapy regimens since it permits the body to heal itself. However, previously available thermotherapy solutions share, as an inherent disadvantage, a tendency to heat the skin to the point of causing a burn when sufficient RF energy is applied to heat the fat cell target in the deepest skin layer. .

The currently accepted RF technique for heating of biological tissues involves exposing the tissue to RF voltage, which produces RF conductive current through the tissue at a level sufficient to overcome the tissue resistance. The current heats the tissue. This method causes uneven heat accompanied by burning of the outer layer(s) the skin. As a result, systems for implementation of this method share, as an inherent disadvantage, a strict requirement for a cooling mechanism to cool the skin during the treatment.

Examples of systems, which require cooling of the skin to prevent burning, include systems disclosed in US Patent No. 6,662,054 assigned to Syneron Medical Ltd. This patent teaches deforming the skin so that a region of skin protrudes from the surrounding skin, and applying RF energy to the protruded skin. The system includes one or more RF electrodes, configured to apply conducted RF current to the skin, and a skin deformer, so that a region of skin protrudes out from surrounding skin and is exposed to the conducted RF current, which follows the deforming act.

Additional examples of prior art systems which require cooling of the skin to prevent burning include those disclosed in US Patent Application No. 20040002705 assigned to Thermage, Inc. which teaches a method of creating a tissue effect by delivering electromagnetic energy through a skin surface from an electromagnetic energy delivery device coupled to an electromagnetic energy

source. At least one of the electromagnetic energy delivery device or electromagnetic energy source includes a memory. A reverse thermal gradient is created through the skin surface to sufficiently heat an underlying tissue site to provide that the temperature of the skin surface is lower than the temperature of the underlying tissue. The reverse thermal gradient is established by use of a cooling system, which is an inherent disadvantage.

Further additional examples of prior art systems which require cooling of the skin to prevent burning include those disclosed in US Patent Application No. 2004030332 and US Patent No. 5919219 assigned to Thermage, Inc., which teach a system and method for providing treatment to a skin surface by applying RF energy through the skin using a memory for gathering information. These systems include, as an inherent disadvantage, a strict requirement for a cooling lumen for receiving cooling fluid and a number of RF electrodes. The RF electrodes are provided to transfer RF current to the skin and are configured to be capacitive coupled to the skin surface, thus creating a heating effect through RF conducted current.

In summary, all previously available methods require the use of a cooling system to cool the outer skin layer throughout the RF treatment. Further, many of the previously available solutions require a memory unit to store local information pertaining to the treated area throughout the treatment. Further, many of the previously available solutions require extensive preliminary adjustments, such as local impedance matching, prior to each treatment. Further, despite use of the phrase "one or more electrodes in many prior art documents, all previously available alternatives share, as an inherent disadvantage, a strict requirement for a return electrode to receive the RF currents after passing tissue being treated. This return electrode for volumetric treatment of adipose tissue (e.g. cellulite) routes a majority of energy through blood and lymphatic vessels. Fat cells are heated only by heat dissipated from these non-target tissues as a result of their inherent resistance.

There is thus a widely recognized need for, and it would be highly advantageous to have, an improved system and method for heating biological tissue via RF energy devoid of the above limitation(s).

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a system for RF (HF) energy treatment of deep layers of human tissue (e.g.dermis and/or hypodermis) to achieve adipose tissue contraction and/or cellulite reduction.

The system includes an RF-energy applicator (e.g.spherical shape) which serves as RF-energy irradiating antenna that functions in combination with an adjacent tissue as a losses transmission line when contacted with epidermis of the tissue.

The system further includes a treated area (part) of human tissue placed in direct contact with RF-energy applicator whereas underlying subcutaneous tissues acts as a dissipative load of the said applicator.

The system further includes a parallel resonance circuit (RF-resonator) including inductor and capacitor and maximally closely contacted with the said applicator by its central point whereas merit factor of this resonant circuit must be sufficiently high that provides active losses determined by equivalent resistance at least 20 times higher that modulus of impedance of a said area of attached human tissue

The system further includes impedance matching network (IMN) converting the impedance of treated area of human tissue into 50 Ohms in order to minimize reflected power from human tissue

The system further includes a phase shifting device at the input of the IMN providing an achievement of maximum of RF-wave at a predetermined depth under the surface or on the surface.

According to another aspect of the present invention there is provided a method, which includes operation of the system.

According to further features in preferred embodiments of the invention described below the applicator is made from Al, Ag, Au, copper, or copper and aluminum alloys and coated with dielectric material.

According to still further features in the described preferred embodiments the applicator is made from Al coated by alumina.

According to still further features in the described preferred embodiments the applicator is moved on the surface of treated skin.

According to still further features in the described preferred embodiments a the feeding cable connects RF- applicator and RF-resonator with impedance matching systems.

According to still further features in the described preferred embodiments the feeding cable has resonance ($n*\lambda/2$) length, where λ- is a wavelength of RF-energy in the cable material and n – is whole number

According to still further features in the described preferred embodiments the impedance matching system provides compensation of the reactance of the attached piece of human tissue.

According to still further features in the described preferred embodiments the impedance matching system is fixed L, T or π- shape structure.

According to still further features in the described preferred embodiments the impedance matching system is broadband impedance transformer.

According to still further features in the described preferred embodiments the impedance matching system is variable.

According to still further features in the described preferred embodiments the phase shifter is trombone type.

According to still further features in the described preferred embodiments the phase shifter is constructed of coaxial cable.

According to still further features in the described preferred embodiments the phase shift provided by the phase shifter is variable in time.

According to still further features in the described preferred embodiments the impedance meter (sensor) is inserted between matching system and RF-applicator.

According to still further features in the described preferred embodiments the said impedance matching system is controllable by feedback system obtaining the signal from the said impedance meter (sensor) for the purpose of reaching the optimal impedance matching and maximal energy deposition into human tissue.

According to still further features in the described preferred embodiments the the coupled energy is delivered from RF-generator (amplifier).

According to still further features in the described preferred embodiments the delivered RF-power is coupled in continuous or pulsing mode.

According to still further features in the described preferred embodiments the control of the energy coupled to human tissue is achieved by variation of amplitude or duty cycle of RF-power in pulsing mode (PWM- control).

According to still further features in the described preferred embodiments the certain part of human body is in contact with second point of the said RF-resonator (for example ground).

According to still further features in the described preferred embodiments the operation is provided on the resonance frequency of human body.

According to still further features in the described preferred embodiments the treatment with RF-applicator t is combined with the laser treatment.

According to still further features in the described preferred embodiments the treatment with RF-applicator t is combined with ultrasonic treatment

According to still further features in the described preferred embodiments the the treatment with RF-applicator t is combined with UV-treatment

According to still further features in the described preferred embodiments the treatment with RF-applicator t is combined with plasma treatment

According to still further features in the described preferred embodiments the treatment with RF-applicator t is combined with flash-lamp treatment

The present invention successfully addresses the shortcomings of the presently known configurations by providing an improved system and method for heating biological tissue via RF energy, which relies upon a single electrode and does not require a cooling system to prevent burning of skin.

Implementation of the method and system of the present invention involves performing or completing selected tasks or steps manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of preferred embodiments of the method and system of the present invention, selected steps could be implemented by hardware or by software on any operating system of any firmware or a combination thereof. For example, as hardware, selected steps of the invention could be implemented as a chip or a circuit. As software, selected steps of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In any case, selected steps of the method and system of the invention could be described as being performed by a data processor, such as a computing platform for executing a plurality of instructions.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 is a simplified schematic diagram illustrating RF-power coupling to a treated tissue according to the present invention.

FIG. 2 is simplified schematic diagram of RF-system according to the present invention illustrating the principles of output power control with PWM and treating space control with phase shifting of incident RF-wave in accordance with a preferred embodiment of the present invention

FIG. 3 illustrates an impedance matching system in accordance with the present invention.

DESCRIPTION OF PREFERRED EMBODIMENT

The present invention is of an improved system and method for heating biological tissue via RF energy, which requires only a single electrode. Specifically, control of phase and duty cycle of applied RF waves through the single electrode of the present invention obviate the need for cooling of the skin surface while facilitating efficient heating of underlying layers of tissue such as dermis and subcutaneous layers. As a result, the desired heating and contraction of adipose tissues is achieved. This allows, for the first time, non-invasive cellulite reduction.

The principles and operation of an improved system and method for heating biological tissue via RF energy according to the present invention may be better understood with reference to the drawings and accompanying descriptions.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. In addition, it is

to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

The present invention offers several advantages with regard to previously available alternatives.

A single electrode, or applicator, employed without a ground electrode permits homogeneous application of RF-energy, which is directed primarily towards rotation, and vibration of dipole molecules, especially water molecules, in the applied electromagnetic field

Phase shifting techniques provide the possibility of concentration of RF-energy at a predetermined depth with respect to the skin surface by variation of position of RF-wave maximum

Organization of energy dissipation inside of subcutaneous tissue insures maintenance of a relatively low temperature on the skin surface (epidermis). This provides a reverse thermal gradient without use of an external cooling system.

Preferably, an Alumina- ceramic-coated applicator minimizes energy losses and prevents unwanted conductive current through human tissue

A supporting parallel resonator attached in proximity to the applicator accumulates RF-energy and provides efficient excitation of the applicator and high RF-voltage on the application surface.

Application of high RF-power in short-pulses provides fast and effective heating of cellulite capsules with relatively low average RF-power level.

PWM-control of output RF-power and simple IMN techniques provide good matching and low RF-power reflection with all types of human tissues. The additional advantage of applied fixed IMN and PWM-control ensure good impedance matching with variable types of human tissue without complicated impedance matching correction. The RF-applicator can be moved on the treated surface.

It will be appreciated that volumetric fatty tissue treatment requires deployment of a homogeneous RF-wave (through cross-section transversal to

wave propagation) with maximum at a desired distance from the electrode-applicator. This homogeneous and high intensity RF-wave insures efficient heating of cellulite capsules and fat cells because of their poor thermal conductivity. In contrast, whereas blood and lymphatic vessels will not be subject to undesired heating because the natural circulation of liquid in these vessels provides convective cooling.

Referring now to the figures, principle components of a system according to the present invention and their operation are explained in greater detail.

The present invention relies upon RF-heating of biological tissues via rotation of molecules of the water molecules **1** (fig.1), which are dipole structures, in an alternating electromagnetic fields. In order to avoid a conductive HF-current a dielectric barrier **2** provides insulation between the applicator 3 and a biological tissue surface 6.

Preferably, applicator **3** is constructed from aluminum or an aluminum alloy covered by alumina coating with a thickness 40-50 μm. Applicator **3** serves also to cool tissue surface **6**, thereby obviating the need for a separate cooling system.

Applicator **3** can be also described as an antenna coupler that irradiates the RF-wave into deep tissue **4**. The *resultant* dissipation of the energy load can be described as irradiative coupling of RF-energy.

The area through which applied RF energy is primarily applied **5** is determined by the contact area between tissue surface **6** and applicator **3** and by the phase of incident electromagnetic wave pulses **17**. The energy diverges from surface **6** and is effectively dissipated **5** through tissue **4**. The depth of RF-energy penetration depends on RF-power and area of applicator and phase shift of electromagnetic wave. By application of phase shifting device **14** it is possible to adjust a position of energy dissipation zone **5** and to coincide with a selected target (e.g. cellulite lesions).

The applied oscillating RF-field stimulates all dipole molecules (mostly water molecules 1) to rotate and vibrate with consequent heating of energy dissipation

zone 5. Zone 5 may be controlled by phase shifting device **14** between RF-generator **10** and applicator **3**. Heating will be primarily in adipose tissue because it is rich in liquids but not subject to convective cooling as blood vessels are. Thus, collagen capsules will be destroyed by heating because their high thermo isolation. The pulse width modulation (PWM) control **12** of output RF- power that provide a possibility to keep a high peak RF-power with low average power level will leads to the most efficient collagen capsule destruction.

It is an advantage of the present invention that epidermal layer **6** is heated much less than subcutaneous tissue **4**. An inverse thermal gradient that is provided by intensive cooling of epidermis that described by Thermage patents is achieved automatically with deep heating of tissues.

The absence of a second or ground electrode in the pictured configuration permits free propagation of RF waves inside tissue **4**.

In order to maximize transmission of RF-energy from RF-source **10** (Figure 2) through resonant cable **7** to applicator **3**, it is connected to the central point of a parallel resonator **13** including a capacitor 8 and an inductor 9 connected in parallel and characterized by very high-Q- factor for example more than 20.

The delivered oscillating RF-power (e.g. 25-300 watts) is stored in the resonator **13** therefore an active (dissipative) load of resonator **13** is only an adjacent tissue.

The active losses of resonator **13** are very low (20-50 times less than energy dissipated inside tissue **4**). The intermittent discharge of capacitor **18** and the inductor **19** is coupled through applicator **3** to tissue **4**.

RF-generator **10** capable of producing 200-400 Watts full power at 40.68 MHz operating frequency demonstrates an optimal performance at 50 Ohms resistive load. Optimal performance means minimal reflected RF-power with maximum RF-forward power dissipated by a load. Thus, the real load that includes treated volume **5** of tissue **4** is matched as 50 Ohms load.

The used impedance matching network (IMN; **11**; see Fig.2) is fixed (the elements are not variable operatively), therefore operation occurs without RF-power amplitude changes. The control of output power is reached by PWM-control (pulse width modulation). PMW achieves modulation of output power by rectangular power pulses applied with a frequency lower than that of the RF wave. In order to decrease RF-power coupling it is necessary to reduce a duty cycle of PWM. PWM-controller **12** produces rectangular pulses with a modulation frequency range of 2-10 kHz. The duty cycle may be varied from 5 to 100%. The shape of RF-power pulse **17** is showed in Fig.2. The PWM-control of output RF-power permits high peak RF-power level in heating zone **5** with lower average power. This provides efficient heating of adipose capsules with minimal impact on blood vessels and other tissues.

The reflected RF-power is 1-2 % of output power therefore 98% of output power is dissipated in the treated volume. Typically, we concentrate energy in adipose tissue therefore coupled RF-energy is dissipated by fat cells, cellulite capsules and by blood and lymphatic liquids. The energy that produces a useful job in fat cells and cellulite tissue will reach 70-80 % of total energy coupled to the volume. The rest energy is dissipated through diffusion of the heat to the surface and by convection of natural liquids of human body.

Applicator **3** is connected to parallel resonator **13.** *Applicator 3 and resonator 13 are physically* positioned inside of operating hand-piece **22** used for treatment procedure. The IMN-system locates inside the main system **23.** In order to avoid a mismatching phase shift between the applicator **3** and the IMN **11,** the length of cable **7** is equal to the whole number *(n)* of wavelength of RF-energy *(λ)* in the cable material.

In order to reach necessary amplitude under the surface **6** of tissue **4,** a phase shifting system (e.g. trombone-type system **14**) is inserted between output of RF-generator **10** and an input of IMN **11.** The position of the maximum of energy dissipation can be controlled by this phase shifting system and can be placed under

surface **6** of tissue **4**. In order to control the depth of RF-energy penetration the length of trombone can be shortened that change a position of dissipated electromagnetic wave in the tissue or an area of the maximum of RF-voltage. Consequently, RF-energy will be dissipated most efficiently in the volume around maximum of the RF-voltage.

The phase shifter **14** can be controlled automatically, for example by motors **15**. This change of phase could be linear or periodical that provides a displacement of maximal heating zone inside the tissue or scanning of maximal heating zone position.

The practical implementation of impedance matching system **11** is illustrated by Fig.3. The RF-power delivered from RF-generator **10** through coaxial cable **16** is modulated by rectangular pulses **17**. Because RF-generator **10** is matched to 50 Ohms and impedance of human tissue is close to 300 Ohms, it is necessary to convert 50 to 300 Ohms with compensation of electromagnetic reactance of tissue **4**. This is achieved with impedance matching network **11**. L-type simple fixed IMN consisting of RF-capacitor **18** and RF-inductor **19** (Fig.3) were applied for this purpose. Half-wave cable **7** is applied for transmission of RF-energy from IMN **11** to RF applicator **3** without phase shifting that is controllable by phase shifting system. The measured impedance in the point **20** is 50 Ohms and in the point **21** is 300 Ohms. Impedance matching networks of various types may be employed without significantly altering performance of the present invention. Regardless of the exact IMN type employed, the IMN **11** can be variably and/or automatically controlled to trace an impedance changing.

WHAT IS CLAIMED:

1. An improved system for heating biological tissue via RF energy having distinguishing characteristics essentially as set forth herein or depicted in the figures.

2. An improved method for heating biological tissue via RF energy having. distinguishing characteristics essentially as set forth herein or depicted in the figures.

3. An improved method for cellulite treatment employing RF energy having distinguishing characteristics essentially as set forth herein or depicted in the figures.

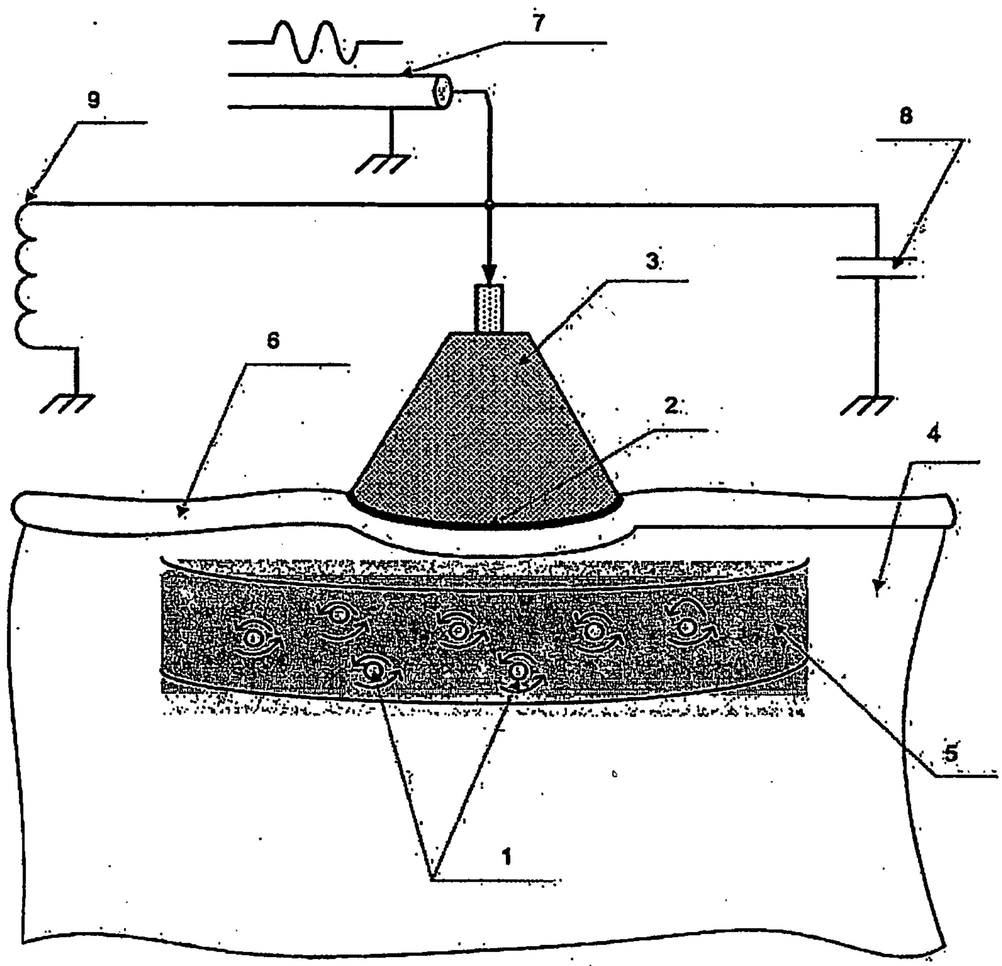

Fig. 1 Application of RF-power to human tissue and heating zone organization.

FIGURE 2

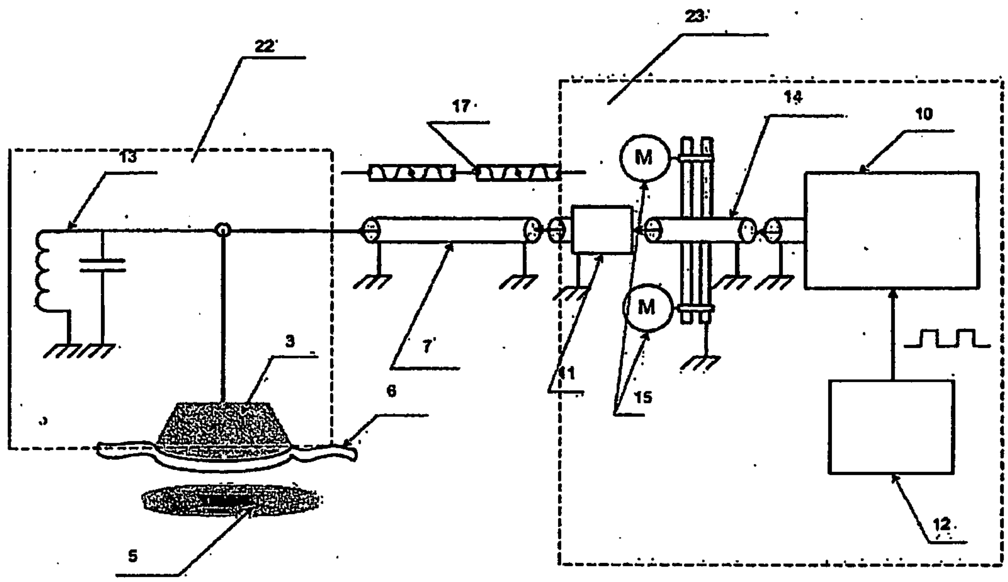

Fig.2 RF-system with controllable heating zone.

FIGURE 3

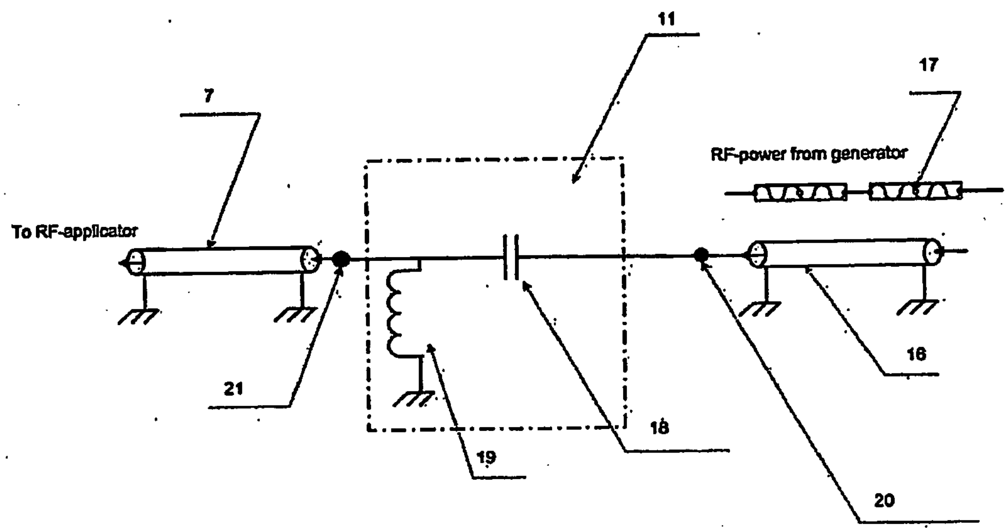

Fig. 3 Impedance Matching Principle

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